ISRCTN19364765 https://doi.org/10.1186/ISRCTN19364765

A randomised controlled trial to compare the efficacy of three new formulations of Ready-to-Use Therapeutic Food (RUTF) in the treatment of severe acute childhood malnutrition

Submission date
16/12/2005

Recruitment status
No longer recruiting

Registration date
23/01/2006

Overall study status
Completed

Last Edited
23/07/2009

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Seal

Contact details
Centre for International Child Health
Institute of Child Health
30 Guildford Street
London
United Kingdom
WC1N 1EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

05CH03

Study information

Scientific Title

Acronym
PRONUT Study

Study objectives
In a population of severely malnourished children:
1. Low-milk/chickpea-based RUTF (Ready-to-Use Therapeutic Food) is non-inferior (one-sided equivalence hypothesis) to high-milk/peanut-based RUTF.
2. Probiotic/Prebiotic enhanced ('Synbiotic 2000 Forte') RUTF is superior to standard RUTF.

Due to a delay in the food acceptability pilot studies, the trial was simplified to test only the second hypothesis:
Probiotic/Prebiotic enhanced ('synbiotic 2000 Forte') RUTF is superior to standard RUTF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Medicine Research and Ethics Committee, Malawi (COMREC) (reference number: P03 /04/236). Final approval, including amendments: 10th November 2005.

Simplification of study to test only second hypothesis approved April 2006.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Severe acute malnutrition

Interventions

The initial plan was that after initial in-patient stabilisation with F75 milk, enrolled children would be randomised to one of four different types of RUTF:
1. (Control) Standard, high-milk/peanut based RUTF
2. Standard RUTF with added synbiotic
3. New formulation low-milk/chickpea-based RUTF
4. New formulation RUTF with added synbiotic

Due to delays in the food acceptability pilot studies, the trial was simplified prior to start, and as of beginning of enrolment in July 2006 is testing only:
1. (Control) Standard, high-milk/peanut based RUTF
2. Standard RUTF with added synbiotic

The simplified study started enrolling patients on 12th July 2006, and is expected to end in April 2007.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Nutritional cure (%)

Secondary outcome measures
1. Death rate (%)
2. Rate of weight gain (g/kg/day)
3. Incidence of illness episodes (including diarrhoea)
4. Length of stay in programme (days)
5. Default rate (%)

Overall study start date
27/01/2006

Completion date
27/04/2007

Eligibility

Key inclusion criteria
All children suffering from severe acute malnutrition (World Health Organisation [WHO] criteria: less than 70% weight/height and/or oedema) admitted to Moyo Malnutrition Ward, Queen Elizabeth Hospital, Blantyre, Malawi

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Initially 1200, after simplification this was changed to 800. Recruitment completed.

Key exclusion criteria
1. Children with severe cerebral palsy or obvious dysmorphic syndrome
2. Children less than six months of age or 4 kg weight

Date of first enrolment
27/01/2006

Date of final enrolment
27/04/2007

Locations

Countries of recruitment
England

Malawi

United Kingdom

Study participating centre
Centre for International Child Health
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
Institute of Child Health, University College London (UK)

Sponsor details
30 Guildford Street
London
England
United Kingdom
WC1N 1EH
+ 44 (0)207 2429789
e.pendleton@ich.ucl.ac.uk

Sponsor type
University/education

Website
http://www.ucl.ac.uk

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
At registration, prior to 23/07/09: Valid International (UK)

Funder Name
Corrected on 23/07/09: the project was funded from a core grant from the Department for International Development (DFID) (UK) to Concern Worldwide (Ireland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/07/2009		Yes	No